We claim:

1. A composition comprising:

a nucleic acid molecule comprising a sequence encoding an antigen; and

an adjuvant which is effective to enhance at least one component of an immune response elicited against the antigen, wherein the adjuvant is present in said composition in a form other than DNA.

2. The composition of claim 1 wherein the nucleic acid molecule is present in a vector construct.

3. The composition of claim 1 wherein the nucleic acid molecule and the adjuvant are coated onto a core carrier particle.

4. The composition of claim 3 wherein the core carrier particle is a gold particle.

5. The composition of claim 1 wherein the nucleic acid molecule and the adjuvant are coated onto gold particles having a nominal size of about 0.1 to 10 μm.

6. The composition of claim 1 wherein the adjuvant is present in the composition in the form of a protein.

7. The composition of claim 1 wherein the adjuvant is present in the composition in the form of a lipid.

8. The composition of claim 1 wherein the adjuvant is present in the composition in the form of a non-protein hormone or an analog thereof.

9. The composition of claim 1 wherein the adjuvant is present in the

composition in the form of a vitamin or an analog thereof.

10. The composition of claim 1 wherein the adjuvant comprises a purified protein derivative of *Bacillus calmette* guerin (BCG).

11. The composition of claim 1 wherein the adjuvant comprises mycobacterial cell wall skeletal material.

12. The composition of claim 1 wherein the adjuvant is monophosphoryl lipid A.

13. The composition of claim 1 wherein the adjuvant is a saponin or a derivative thereof.

14. The composition of claim 13 wherein the adjuvant is Quil-A.

15. The composition of claim 1 wherein the adjuvant is at least partially soluble in ethanol.

16. The composition of claim 1 wherein the adjuvant is an immune shift adjuvant.

17. The composition of claim 1 wherein the antigen is from an infectious or parasitic disease agent.

18. The composition of claim 1 wherein the antigen is from a virus.

19. The composition of claim 18 wherein the virus is selected from the group consisting of a hepatitis B virus (HBV), human immunodeficiency virus (HIV) and an influenza virus.

20. The composition of claim 1 wherein the antigen is from a parasitic disease agent.

21. The composition of claim 20 wherein the antigen is a circumsporozoite (CS) antigen from a malarial parasite.

22. Coated particles suitable for use in particle-mediated nucleic acid immunisation, which particles comprise core carrier particles coated with a composition comprising an adjuvant and a nucleic acid molecule that contains a coding sequence encoding an antigen, wherein the adjuvant is present in the composition in a form other than DNA.

23. Coated particles according to claim 22, wherein said particles are tungsten or gold particles.

24. Coated particles according to claim 22, wherein the antigen is an antigen of a viral, bacterial, parasite or fungal pathogen.

25. Coated particles according to claim 22, wherein the antigen is a tumor-specific antigen or an antigen associated with an autoimmune disease.

26. A particle acceleration device suitable for particle-mediated nucleic acid immunisation, wherein said device is loaded with the coated particles of claim 22.

Rule 1.126

27 23. Use of the composition of claim 1 in the manufacture of a medicament for use in nucleic acid immunization.

28 24. Use of the composition of claim 3 in the manufacture of a medicament

for use in nucleic acid immunization.

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~~25.~~ A method for eliciting an immune response against a selected antigen in an individual, said method comprising delivering the composition of claim 1 directly into cells present at a target site in the individual in an amount sufficient to bring about said immune response.

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~~26.~~ The method of claim ~~25~~ wherein the nucleic acid molecule and the adjuvant are coated onto a core carrier particle.

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~~27.~~ The method of claim ~~26~~ wherein the composition is delivered using a particle-mediated delivery technique.

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~~28.~~ The method of claim ~~25~~ wherein the target site is epidermal tissue.

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~~29.~~ A composition comprising a nucleic acid molecule comprising a sequence encoding an antigen, and an immune shift adjuvant which is effective to enhance the T helper 1 (Th1) component of an immune response elicited against the antigen in an individual receiving said composition, wherein the immune shift adjuvant is present in said composition in a form other than DNA.

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~~30.~~ The composition of claim ~~29~~ 33 wherein the antigen is from an infectious or parasitic disease agent.

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~~31.~~ The composition of claim ~~29~~ 33 wherein the immune shift adjuvant is monophosphoryl lipid A.

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~~32.~~ A pharmaceutical preparation comprising a core carrier particle coated with the composition of claim ~~29~~ 33.

37
~~33.~~ A method for eliciting an immune response against a selected antigen in an individual, said method comprising:

(a) delivering a nucleic acid molecule to cells present at a target site in the individual, wherein said nucleic acid molecule contains a sequence that is expressed within said cells to produce the selected antigen at sufficient levels to elicit an antigen-specific immune response in the individual; and

(b) administering an immune shift adjuvant to the target site, wherein the adjuvant is administered in an amount sufficient to shift the antigen-specific immune response toward a T helper 1 (Th1)-type or a T helper 2 (Th2)-type response.

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~~34.~~ The method of claim ~~33~~ wherein the antigen is from an infectious or parasitic disease agent.

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~~35.~~ The method of claim 33 wherein the nucleic acid molecule is present in a vector construct.

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~~36.~~ The method of claim 33 wherein the nucleic acid molecule is delivered using a particle-mediated delivery technique.

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~~37.~~ The method of claim 33 wherein the immune shift adjuvant is administered topically to the target site.

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~~38.~~ The method of claim 33 wherein the immune shift adjuvant is administered to the target site using a particle-mediated delivery technique.

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~~39.~~ The method of claim 33 wherein the immune shift adjuvant is monophosphoryl lipid A.

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~~40.~~ The method of claim 33 wherein the nucleic acid molecule contains a sequence encoding a circumsporozoite (CS) antigen from a malarial parasite.

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~~41.~~ The method of claim 33 wherein the target site is epidermal tissue.

46
~~42.~~ The method of claim 33 wherein the nucleic acid molecule and the adjuvant are administered concurrently.

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~~43.~~ The method of claim 33 wherein the nucleic acid molecule and the adjuvant are combined to provide a single composition.